General

Guideline Title

Guideline for autologous tissue management.

Bibliographic Source(s)

Van Wicklin SA, Brubaker SA, Conner R. Guideline for autologous tissue management. In: 2015 guidelines for perioperative practice. Denver (CO): Association of periOperative Registered Nurses (AORN); 2014. p. 187-238. [182 references]

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Recommendations

Major Recommendations

Note from the Association of periOperative Nurses (AORN): The original guideline document provides guidance to perioperative personnel for managing autologous tissue in the perioperative setting, including avulsed teeth, cranial bone flaps, parathyroid glands, skin, veins, and dropped autografts. Guidelines are provided for transferring tissue from the sterile field, packaging and labeling, transporting and storing, and handling autologous tissue for delayed replantation or autotransplantation within the same facility. Guidelines for managing autologous adipose tissue are not provided. Currently, adipose aspirates can only be used for immediate autologous fat grafting at the time of recovery, and there is no reliable method for preserving and storing adipose tissue for delayed autotransplantation. Recommendations related to processes for intraoperative storage and cryopreservation of autologous tissue are outside the scope of the original guideline document.

I. Avulsed teeth that cannot be immediately replanted in the patient at the time of avulsion should be placed in a storage medium to help maintain periodontal ligament (PDL) cell viability.
II. The patient's autologous cranial bone flap may be preserved and replanted.
III. The patient's parathyroid tissue may be cryopreserved and autotransplanted.
IV. The patient's autologous skin may be preserved and autotransplanted.
V. The patient's autologous vein may be preserved and autotransplanted.
VI. A multidisciplinary team consisting of the surgeon, perioperative registered nurse (RN), and infection preventionist should conduct a risk assessment to consider the benefits and potential harms associated with replantation or autotransplantation of a contaminated autograft compared with other treatment options (e.g., discarding the graft and using artificial material).
VII. Autologous tissue that will be stored within the facility or health care organization for delayed replantation or autotransplantation should be transferred from the sterile field in a manner that maintains the sterility and integrity of the tissue and prevents exposure of health care personnel to blood, body fluids, or other potentially infectious materials.

VIII. Autologous tissue that will be stored within the facility or health care organization for delayed replantation or autotransplantation should be packaged and labeled in a manner that protects and secures the autograft; prevents cross-contamination and mix-ups during storage; facilitates tissue tracking; and prevents exposure of health care personnel to blood, body fluids, or other potentially infectious materials.

IX. Autologous tissue should be transported in a manner that protects and secures the autograft; maintains the integrity of the tissue; prevents exposure of health care personnel to blood, body fluids, or other potentially infectious materials; and ensures the confidentiality of protected patient information.

X. Autologous tissue intended for delayed replantation or autotransplantation should be stored in a manner that protects and secures the autograft, prevents cross-contamination and mix-ups during storage, and prevents exposure of health care personnel to blood, body fluids, or other potentially infectious materials.

XI. Autologous tissue intended for replantation or autotransplantation should be handled using sterile technique and in a manner that protects and secures the autograft from damage or contamination.

XII. Policies and procedures for the managing autologous tissue must be developed, reviewed periodically, revised as necessary, and readily available in the practice setting (21 Code of Federal Regulations [CFR] 1271, 2013; "Current good tissue practice," 2012; "Standards for tissue banking," 2012; "Transplant safety. In: The Joint Commission. Comprehensive accreditation manual for hospitals," 2014; "Transplant safety. In: The Joint Commission. Comprehensive accreditation manual for ambulatory care," 2014; "Surgical and related services," 2014).

XIII. Perioperative team members should receive initial and ongoing education and complete competency verification activities on the principles and processes of autologous tissue management.

XIV. Nursing activities related to autologous tissue management should be documented in a manner consistent with facility or health care organization policies and procedures, regulatory requirements, (21 CFR 1271, 2013; "Current good tissue practice," 2012) AORN guidelines ("Guideline for perioperative health care information management," 2015), and accreditation agency ("Transplant safety. In: The Joint Commission. Comprehensive accreditation manual for hospitals," 2014; "Transplant safety. In: The Joint Commission. Comprehensive accreditation manual for ambulatory care," 2014; "Surgical and related services," 2014) and American Association of Tissue Banks (AATB) standards ("Standards for tissue banking," 2012).

XV. Perioperative personnel should participate in a variety of quality assurance and performance improvement activities that are consistent with the facility or health care organization plan to improve understanding of and compliance with the principles and processes of autologous tissue management.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Any condition requiring the use of autologous tissue in the perioperative setting, including avulsed teeth, cranial bone flaps, parathyroid glands, skin, veins, and dropped autografts

Guideline Category

Management

Prevention

Clinical Specialty

Nursing

Surgery

Intended Users

Advanced Practice Nurses

Hospitals

Nurses

Guideline Objective(s)

To provide guidance to perioperative personnel for managing autologous tissue in the perioperative setting, including avulsed teeth, cranial bone flaps, parathyroid glands, skin, veins, and dropped autografts

Target Population

Patients undergoing surgical and other invasive procedures in which autologous tissues are used, including avulsed teeth, cranial bone flaps, parathyroid glands, skin, veins, and dropped autografts

Interventions and Practices Considered

1. Storage of avulsed teeth to help maintain periodontal ligament (PDL) cell viability (if immediate replantation is not possible)
2. Preservation (freezing and cryopreservation) and replantation of autologous cranial bone flap
3. Cryopreservation and autotransplantation of parathyroid tissue
4. Preservation and autotransplantation of autologous skin
5. Preservation and autotransplantation of autologous vein
6. Use of a multidisciplinary team to conduct a risk assessment (benefits and potential harms) associated with replantation or autotransplantation of a contaminated autograft
7. Transferring autologous tissue from the sterile field in a manner that maintains the sterility and integrity of the tissue and prevents exposure of health care personnel to blood, body fluids, or other potentially infectious materials
8. Handling, labeling, transportation and storage of autologous tissue in a manner that protects and secures the autograft
9. Establishment and maintenance of policies and procedures for managing autologous tissue
10. Providing initial and ongoing education and competency evaluation of perioperative team members to deliver safe care to patients undergoing operative or other invasive procedures
11. Documentation of nursing activities related to autologous tissue management
12. Participation in a variety of quality assurance and performance improvement activities

Major Outcomes Considered

- Periodontal ligament (PDL) cell viability
- Knowledge about tooth avulsion
- Successful replantation
- Bone flap infection
- Bone cell viability
- Fusion success rate
- Sterility and viability of bone flaps
- Clinical, aesthetic, and functional results
- Surgical site infection
- Bone resorption
- Postoperative complications
- Viability and functionality of cryopreserved parathyroid glands
- Successful engraftment of stored skins
- Prevention of cold storage injury of blood vessels
- Microbial detection and identification and evaluation of bone structure

- Frequency of positive and negative cultures/sensitivity, specificity, and predictive values/microorganisms

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Evidence Review

On January 24 and January 27, 2014, a medical librarian conducted a systematic search of the databases MEDLINE®, CINAHL®, and the Cochrane Database of Systematic Reviews for meta-analyses, systematic reviews, randomized controlled and non-randomized trials and studies, case reports, letters, reviews, and guidelines. The librarian also searched Scopus®, although not systematically. Search terms included *autologous transplantation, tissue preservation, organ transplantation, preservation, storage, storage solution, saline solution, isotonic saline, potassium chloride, N-acetylhistidine, ice, cold temperature, bone flap, bone transplantation, skull, bone and bones, surgical flap, saphenous vein, radial artery, renal artery, mammary artery*, and *thoracic artery*. During the development of this document, the lead author also requested supplementary searches on the topics of storage media, preservation of avulsed teeth, and the use of swab cultures.

The initial search was limited to literature published in English since January 2006; however, the time restriction was not considered in subsequent searches. At the time of the initial search, the librarian also established weekly alerts on the topics included in the initial search. The librarian later added terms from subsequent supplementary searches to the alerts and, until May 2014, presented relevant results to the lead author.

The lead author reviewed search results from the medical librarian's literature search for the Association of periOperative Registered Nurses (AORN) Guideline for Specimen Management to identify literature specific to management of other tissues and the preservation of avulsed teeth. During the development of the document, the lead author requested additional articles and other literature that either did not fit the original search criteria or was discovered during the evidence appraisal process. Finally, the lead author and the medical librarian identified relevant guidelines from government agencies and standards-setting bodies.

Excluded were non-peer-reviewed or retracted publications; evidence specific to organ transplantations, processes for cryopreservation, and surgical techniques and treatment protocols; and some evidence related to allografts, intraoperative storage of autologous tissue, and educational needs surrounding traumatic dental injuries not specific to health care workers.

See Figure 1 in the original guideline document for a flow diagram of literature search results.

Number of Source Documents

182 full-text sources were cited in the guideline.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

I: Randomized controlled trial (RCT) or experimental study, systematic review of all RCTs

II: Quasi-experimental study, systematic review of quasi-experimental studies or combination of quasi-experimental and RCTs

III: Non-experimental studies, qualitative studies, systematic review of non-experimental studies, combination of non-experimental, quasi-experimental, and RCTs, or any or all studies are qualitative

IV: Clinical practice guidelines, position or consensus statements

V: Literature review, expert opinion, case Report, community standard, clinician experience, consumer experience, organizational experience (quality improvement, financial)

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Articles identified in the search were provided to the lead author and the assigned evidence reviewer for review and critical appraisal using the Association of periOperative Registered Nurses (AORN) Evidence Rating Model Research or Non-Research Evidence Appraisal Tools as appropriate. The literature was independently evaluated and appraised by the lead author and the evidence reviewer according to the strength and quality of the evidence. Each article was then assigned an appraisal score determined by consensus. The appraisal score is noted in brackets after each reference, as applicable. Various articles also were provided to an expert member of the project team for consideration regarding relevance and application of the evidence for determining practice guidelines.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

The evidence supporting each intervention and activity statement within a specific recommendation was summarized, and the Association of periOperative Registered Nurses (AORN) Evidence-Rating Model was used to rate the strength of the collective evidence. Factors considered in the review of the collective evidence were the quality of the evidence, the quantity of similar evidence on a given topic, the consistency of evidence supporting a recommendation, and the potential benefits and harms. The assigned evidence rating is noted in brackets after each intervention and activity statement in the original guideline document.

Rating Scheme for the Strength of the Recommendations

1: Strong Evidence: Interventions or activities for which effectiveness has been demonstrated by strong evidence from rigorously-designed studies, meta-analyses, or systematic reviews, rigorously-developed clinical practice guidelines, or regulatory requirements.

- Evidence from a meta-analysis or systematic review of research studies that incorporated evidence appraisal and synthesis of the evidence in the analysis.
- Supportive evidence from a single well-conducted randomized controlled trial.
- Guidelines that are developed by a panel of experts, that derive from an explicit literature search methodology, and include evidence appraisal and synthesis of the evidence.

1: Regulatory Requirement: Federal law or regulation.

2: Moderate Evidence: Interventions or activities for which the evidence is less well established than for those listed under "1: Strong Evidence."

- Supportive evidence from a well-conducted research study.
- Guidelines developed by a panel of experts which are primarily based on the evidence but not supported by evidence appraisal and synthesis of the evidence.
- Non-research evidence with consistent results and fairly definitive conclusions.

3: Limited Evidence: Interventions or activities for which there are currently insufficient evidence or evidence of inadequate quality.

- Supportive evidence from a poorly conducted research study.
- Evidence from non-experimental studies with high potential for bias.
- Guidelines developed largely by consensus or expert opinion.
- Non-research evidence with insufficient evidence or inconsistent results.
- Conflicting evidence, but where the preponderance of the evidence supports the recommendation.

4: Benefits Balanced with Harms: Selected interventions or activities for which the Association of periOperative Registered Nurses (AORN) Recommended Practices Advisory Board (RPAB) is of the opinion that the desirable effects of following this recommendation outweigh the harms.

5: No Evidence: Interventions or activities for which no supportive evidence was found during the literature search completed for the recommendation.

- Consensus opinion

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

The Guideline for Autologous Tissue Management has been approved by the Association of periOperative Registered Nurses (AORN) Guideline Advisory Board. It was presented as a proposed guideline for comments by members and others. The guideline is effective November 15, 2014.

Evidence Supporting the Recommendations

References Supporting the Recommendations

21 CFR 1271: Human cells, tissues, and cellular and tissue-based products. [internet]. Silver Spring (MD): US Food and Drug Administration; 2013 Apr [accessed 2014 Sep 26].

Current good tissue practice (CGTP) and additional requirements for manufacturers of human cells, tissues, and cellular and tissue-based products (HCT/Ps). Silver Spring (MD): US Food and Drug Administration; 2012.

Guideline for perioperative health care information management. In: Guidelines for perioperative practice. Denver (CO): AORN, Inc.; 2015. p. 491-512.

Standards for tissue banking. McLean (VA): American Association of Tissue Banks; 2012.

Surgical and related services. In: Accreditation handbook for ambulatory health care. Skokie (IL): Accreditation Association for Ambulatory Health Care; 2014. p. 52-5.

Transplant safety. In: The Joint Commission. Comprehensive accreditation manual for ambulatory care edition. Washington (DC): The Joint Commission; 2014 Mar.

Transplant safety. In: The Joint Commission. Comprehensive accreditation manual for hospitals edition. Washington (DC): The Joint Commission; 2014 Mar.

Type of Evidence Supporting the Recommendations

The literature was independently evaluated and appraised by the lead author and the evidence reviewer according to the strength and quality of the evidence. Each article was then assigned an appraisal score determined by consensus. The appraisal score is noted in brackets after each reference in the original guideline document, as applicable. Also see the original guideline document for the systematic review and discussion of evidence.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Patient tissues intended for replantation or autotransplantation are recovered, processed, packaged, labeled, stored, tracked, and replanted or autotransplanted in a manner that minimizes microbial growth, prevents mix-ups, and reduces the risks for errors. Refer to the original guideline document for additional discussion of potential benefits of specific interventions.

Potential Harms

- The harms associated with immediate replantation of an avulsed tooth are that the tooth replantation may be performed incorrectly. Replantation of a tooth that is contaminated with debris may increase the patient's risk for infection.
- The harms associated with the use of autologous bone for reconstructive cranioplasty include the potential for infection from contaminated cranial bone grafts, and bone nonviability and resorption, particularly in pediatric patients.
- The harms associated with frozen or cryopreserved storage of autologous cranial bone flaps are that the autograft may be contaminated during storage or during the recovery or replantation procedure. The process of cryopreservation and long-term storage may lead to mechanical instability (e.g., crack formation) of the bone or surface abrasiveness that facilitates bacterial adhesion and colonization. Long-term storage of autologous tissue carries with it the potential for mix-ups if autograft labeling methods are inadequate (e.g., smudging of identifiers during cold storage, labels separating from the package), and contamination or cross-contamination if the graft's packaging material is not validated for use at the storage temperature selected.
- The harms associated with cryopreservation and autotransplantation of patients' parathyroid tissue include the need for a secondary surgery, increased cost, and the increased potential for infection from transplanting contaminated or nonviable autologous parathyroid tissue. There is an increased risk of autograft failure with cryopreserved tissue compared with fresh tissue. Parathyroid tissue may be destroyed by the cryopreservation process or degraded to the extent that insufficient parathyroid hormone is released after autotransplantation.
- The harms associated with subcutaneous storage of autologous cranial bone flaps are that the procedure requires additional surgical time and may require an additional surgical incision, and the graft may be contaminated during recovery, during storage, or during the replantation procedure. Patients may experience discomfort from the stored autograft, and osteoclast activity may cause the autograft to diminish in size during subcutaneous storage.
- The harms associated with storing autologous skin for delayed autotransplantation include the increased potential for infection from contaminated or nonviable autologous skin grafts.
- The harm associated with storing the patient's autologous vein for delayed autotransplantation is the increased potential for infection from contaminated or nonviable autologous vein grafts.
- The harm associated with replantation or autotransplantation of contaminated autologous grafts is the increased potential for the patient to develop a surgical site infection.
- The harm associated with culturing tissue to determine the level and identity of microbial growth on autologous tissue surfaces is that the patient may receive unnecessary antibiotics or other treatments to prevent infection.

Qualifying Statements

Qualifying Statements

- These recommendations represent the Association's official position on questions regarding optimal perioperative nursing practice.
- No attempt has been made to gain consensus among users, manufacturers, and consumers of any material or product.
- Compliance with the Association of periOperative Registered Nurses (AORN) guideline is voluntary.
- AORN's recommendations are intended as achievable and represent what is believed to be an optimal level of patient care within surgical and invasive procedure settings.
- Although they are considered to represent the optimal level of practice, variations in practice settings and clinical situations may limit the degree to which each recommendation can be implemented.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Mobile Device Resources

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Staying Healthy

IOM Domain

Effectiveness

Safety

Identifying Information and Availability

Bibliographic Source(s)

Van Wicklin SA, Brubaker SA, Conner R. Guideline for autologous tissue management. In: 2015 guidelines for perioperative practice. Denver (CO): Association of periOperative Registered Nurses (AORN); 2014. p. 187-238. [182 references]

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2014

Guideline Developer(s)

Association of periOperative Registered Nurses - Professional Association

Source(s) of Funding

Association of periOperative Registered Nurses (AORN)

Guideline Committee

Association of periOperative Registered Nurses (AORN) Recommended Practices Advisory Board

Composition of Group That Authored the Guideline

Lead Author: Sharon A. Van Wicklin, MSN, RN, CNOR, CRNFA, CPSN, PLNC, Perioperative Nursing Specialist, AORN Nursing Department, Denver, CO

Contributing Authors: Scott A. Brubaker, CTBS, Chief Policy Officer, American Association of Tissue Banks, McLean, VA; Ramona Conner, MSN, RN, CNOR, Manager, Standards and Guidelines, AORN Nursing Department, Denver, CO

Team Members: Marie A. Bashaw, DNP, RN, NEA-BC, CNOR, Clinical Assistant Professor, Wright State University College of Nursing and Health, Dayton, OH; Patricia Graybill-D'Ercole, MSN, RN, CNOR, CHL, CRCST, Clinical Specialist, Integra Life Science, York, PA; Deborah Farina Mulloy, PhD, RN, Associate Chief Nurse, Quality and Center for Nursing Excellence, Brigham and Women's Hospital, Boston, MA

Financial Disclosures/Conflicts of Interest

No financial relationships relevant to the content of this guideline have been disclosed by the authors, planners, peer reviewers, or staff.

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Electronic copies: Available to subscribers from the Association of periOperative Nurses (AORN) Web site .

Print copies: Available for purchase from the AORN Web site .

Availability of Companion Documents

The following is available:

- Autologous tissue management evidence table. 2014. 41 p. Electronic copies: Available from the Association of periOperative Nurses (AORN) Web site .

In addition, an AORN Guidelines for Perioperative Practice eBook mobile app is available from the AORN website .

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI Institute on January 9, 2015. The information was verified by the guideline developer on February 25, 2015.

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